PACKAGE LEAFLET: INFORMATION FOR THE USER

Pancuronium Bromide 2 mg/ml Injection

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Pancuronium Bromide Injection is and what it is used for
2. Before you use Pancuronium Bromide Injection
3. How to use Pancuronium Bromide Injection
4. Possible side effects
5. How to store Pancuronium Bromide Injection
6. Further information

1. WHAT PANCURONIUM BROMIDE INJECTION IS AND WHAT IT IS USED FOR

Pancuronium bromide is one of a group of medicines called ‘non-depolarising’ muscle relaxants.

Pancuronium Bromide Injection is used to relax muscles during surgery, including caesarean section and in intensive care.

2. BEFORE YOU USE PANCURONIUM BROMIDE INJECTION

Do not use Pancuronium Bromide Injection

- if you have shown signs of hypersensitivity (severe allergy) to pancuronium or bromide in the past

Tell your doctor if the above applies to you before this medicine is used.

Take special care with Pancuronium Bromide Injection

- if you have kidney, liver, lung or heart disease
- if you have high blood pressure
- if you have cancer, particularly lung cancer
- if you suffer from any of the following conditions: myasthenia gravis, myasthenic syndrome (other neuromuscular diseases) or poliomyelitis
- if you have fluid retention (you may have swelling around the ankles)
- if you have jaundice

Tell your doctor if any of the above applies to you before this medicine is used.
Special care will also be taken in the elderly, newborn babies, patients who are dehydrated or in general poor health and patients who have blood abnormalities, such as altered calcium, magnesium, potassium and protein levels (the doctor may do blood tests to check for such abnormalities).

**Taking/using other medicines**

Pancuronium bromide must not be administered along with a “depolarising” muscle relaxant, e.g. suxamethonium.

Other medicines used/taken at the same time as pancuronium bromide may interact, hence, special care may be needed, for example:

- other muscle relaxants of the ‘non-depolarising’ type (e.g. mivacurium)
- some anaesthetic agents (e.g. halothane, ether, enflurane, isoflurane, methoxyflurane, cyclopropane, thiopentone, methohexitone, ketamine, fentanyl, gamma-hydroxybutyrate, etomidate)
- anticancer medicines belonging to a group called ‘alkylating agents’ (including medicines known as ‘nitrogen mustards’)
- some antibiotics (e.g. aminoglycosides, metronidazole) and antifungal medicines (e.g. imidazoles)
- medicines affecting the heart or blood pressure (glyceryl trinitrate, propranolol, adrenaline, noradrenaline, alpha blockers, beta blockers, quinidine)
- water tablets (diuretics)
- medicines used to control anxiety (diazepam)
- antidepressants (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- strong pain-killers (e.g. narcotics)
- steroid medicines
- medicines used to treat a disease affecting the muscles called 'myasthenia gravis' (neostigmine, pyridostigmine, edrophonium)
- phenytoin (antiepilepsy medicine)
- heparin and protamine (medicines used to control the ease with which the blood will clot)
- azathioprine (a medicine used to prevent transplant rejection)
- theophylline (a medicine used to treat some breathing disorders)
- medicines used to increase the level of some salts in the blood (potassium chloride, sodium chloride, calcium chloride)
- vitamin B₁ (thiamine) if taken in high doses
- magnesium sulphate (used in the treatment of constipation, pre-eclampsia, abnormal heart rhythms)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and breast-feeding**

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

Ask your doctor or pharmacist for advice before taking any medicine.
Driving and using machines
Do not drive or use machines for 24 hours after full recovery from the muscle relaxant effects of pancuronium bromide.

Important information about one of the ingredients of Pancuronium Bromide Injection
This medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. essentially ‘sodium free’.

3. HOW TO USE PANCRURONIUM BROMIDE INJECTION

This medicine will be given to you as an injection into a vein.

Dose
The dose of medicine given to you will depend upon your age, your weight, expected duration of surgery, drugs that have been given to you previously and how well your kidneys and liver are working.

The dose range in adults is typically between 50 and 100 micrograms/kg bodyweight.

If you are given too much or too little Pancuronium Bromide Injection
This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. POSSIBLE SIDE EFFECTS

Like all medicines, pancuronium bromide can cause side effects, although not everybody gets them.

During use of Pancuronium Bromide Injection your doctor will be observing you for:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint

If this serious side effect occurs, urgent medical attention will be needed.

After you have come round, if any of the following happen, tell your doctor as soon as possible:

- breathing difficulties
- unusually rapid heart beat, palpitations or irregular heart beat
- pain, itching, local skin reaction or irritation particularly around the injection site
- problems with your vision
- skin rash
- excess production of saliva
Your doctor may monitor for changes in your blood pressure.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. **HOW TO STORE PANCURONIUM BROMIDE INJECTION**

Keep out of the reach and sight of children

**Expiry**
This medicine must not be used after the expiry date which is stated on the vial ampoule and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

**Storage**
The ampoules should be kept in the outer carton, in order to protect from light, and stored in a refrigerator. They should not be frozen.

6. **FURTHER INFORMATION**

**What Pancuronium Bromide Injection contains**
The active substance is pancuronium bromide. Each millilitre (ml) of solution contains 2 milligrams (mg) of pancuronium bromide.

The other ingredients are sodium chloride, sodium acetate, and Water for Injections.

**What Pancuronium Bromide Injection looks like and contents of the pack**
Pancuronium Bromide Injection is a clear, colourless solution for injection which comes in glass containers called ampoules.

It may be supplied in packs containing:
- 5 x 4 mg/2 ml ampoules
- 10 x 4 mg/2 ml ampoules
- 50 x 4 mg/2 ml ampoules

Not all packs may be marketed.

**Marketing authorisation holder and manufacturer**
Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK

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Pancuronium Bromide 2 mg/ml Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Do not mix other solutions in the same syringe as a change in pH can cause precipitation.

Instructions for use and handling
For single use only

Any unused solution should be discarded.

It is not recommended to give this product by infusion.